

Response to questions from Julien Farland sent on 3/21/12 regarding the rDNA permit

- 1) *The name of the institution listed on the permit application includes both BUMC and BMC. Are those separate locations? If so, please explain.*

Boston University is primarily comprised of the Charles River Campus (CRC) and Boston University Medical Campus (BUMC). Recombinant DNA and biohazardous research are conducted on both campuses. The Boston Medical Center (BMC) and Boston University (BU) are two distinct, separate organizations. Boston University, however, oversees the research that is conducted by BMC, and all of BMC's recombinant DNA (rDNA) and biohazardous research is reviewed by BU's IBC. The BUMC campus includes the School of Medicine, School of Dental Medicine, and School of Public Health as well as BMC.

- 2) *The description of the RDNA health and safety program states that the PI is required to complete annual on-line Recombinant DNA training. Please state how other laboratory staff and IBC members are trained on Recombinant DNA and IBC policies.*

In accordance with BU's Biosafety Manual, the Principal Investigators are responsible for ensuring "that specific laboratory hazards are effectively communicated to laboratory personnel; and personnel have received appropriate training and are competent to perform procedures used in the laboratory..." In addition, all laboratory staff and workers are required to complete annual Laboratory Safety Training, which includes general laboratory safety, biological safety practices, emergencies, and occupational health. The classes are offered through web-based training modules as well as in-classroom training sessions. Additional information on training is also available in the Biosafety Manual. Please refer to Chapter 6 of the Biosafety Manual for additional information.

IBC members are trained at each convened meeting on a variety of applicable topics. In addition, specific training is done on a case-by-case basis depending on what the research applications contain. All new members of the IBC are given a manual on the duties, responsibilities, and functions of the Committee and meet with the IBC staff for a formal training session.

- 3) *The section on the medical surveillance program should describe how and when incidents with Recombinant DNA and exposures/incidents with BSL3 and agents will be reported to Boston Public Health Commission.*

Incidents involving recombinant DNA and exposures/incidents with BSL3 agents are reported to the BPHC according to the "Boston University and Boston Medical Center Research Compliance Policy on Disease Surveillance and Reporting for High-Risk Agents". That policy implements the BPHC's Guidelines for Implementation and Enforcement of Boston Public Health Commission's Disease Surveillance and Reporting Regulation. BPHC receives timely access to information regarding incidence of disease syndromes, any outbreak or cluster of a disease, and potential exposures to reportable diseases deemed harmful to the public health (including rDNA and BSL-3 agents). Please refer to Appendix U of the Biosafety Manual for a full copy of BU's policy.

4) *How many laboratories at the VA will be using recombinant DNA? Will BU inspect those labs annually? Will someone from the VA be on the BU VA? If not, there should be a formal method of communication between the BU IBC and the VA.*

Approximately five laboratories at the VA will be using rDNA; the exact numbers will be determined once the IBC reviews all of the proposed rDNA applications. BU EHS will conduct lab visits associated with the rDNA protocols in the same manner as how it is done for BU rDNA protocols. In addition, BU EHS will also be in communication with the VA's EHS group on all applicable matters.

The agreement between BU and VA for use of BU's IBC is only good for one year. While we do not anticipate recruiting a VA staff member to serve on the IBC, the IBC Office will coordinate, work closely, communicate directly and send copies of all meeting minutes and approved VA protocols to the VA. In addition, the VA is required to inform the IBC of any incidents involving rDNA, at which point the IBC will report to the BPHC.

5) Also, BU should submit a map of the areas where the buildings to be permitted are located.

Campus maps are attached. rDNA research could be done anywhere within the properties reflected on the maps provided the space is appropriately zoned and approved for such use.